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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 225, 510, 514, 515, and 558

[Docket No. 97N–0276]

RIN 0910–AB18

Animal Drug Availability Act; Medicated Feed Mill Licenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a final rule amending the new animal drug regulations to implement the medicated feed mill licensing requirements of the Animal Drug Availability Act of 1996 (ADAA). The ADAA amended the Federal Food, Drug, and Cosmetic Act (the act) to require that each facility that manufactures feeds containing approved new animal drugs possess a medicated feed mill license for the facility, rather than a separate medicated feed application (MFA) for each medicated feed manufactured by the facility, as previously required by the act. The final rule implements the feed mill licensing provisions of the ADAA.

EFFECTIVE DATE: *(Insert date 30 days after date of publication in the* **Federal Register.)**

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SUPPLEMENTARY INFORMATION:

I. Background

The ADAA (Public Law 104–250), which amended sections 512(a) and (m) of the act (21 U.S.C. 360b(a) and (m)), replaces the system that required the agency's approval for the

manufacture of specific medicated feeds with a site licensing system for the manufacture of such feeds.

Prior to the passage of the ADAA, an approved MFA was required by the act for the manufacture of medicated feed. The act required a feed mill (referred to also as "feed manufacturer," "feed firm," or "feed manufacturing facility") to submit a separate MFA for each medicated feed manufactured by the firm. The ADAA eliminates this requirement and provides for feed mills to be licensed and allows licensed facilities to manufacture any feed containing an approved new animal drug. Additionally, section 512(m)(6) of the act, as added by the ADAA, provides the agency with the authority, to the extent consistent with the public health, to exempt facilities that manufacture certain types of medicated feed from the requirement of obtaining a medicated feed mill license.

These final regulations implementing section 512(m) of the act as amended by the ADAA require only one facility license for the manufacture of animal feeds containing approved new animal drugs, instead of multiple approved MFA's. Furthermore, those medicated feeds previously exempted from the MFA requirement under § 558.4 (21 CFR 558.4) will also be exempt from the requirement of being manufactured in a licensed feed mill under this regulation.

The ADAA also provided for a transitional license for any feed manufacturing facility that, at the time of enactment of the ADAA, held an approved MFA for the manufacture of a medicated feed . Transitional licenses expired April 9, 1998. The Office of Management and Budget (OMB) approved the paperwork requirements for licensing for a 3-year period on October 31, 1997 (OMB control number 0910-0337).

II. Summary of the Proposed Rule

In the **Federal Register** of July 30, 1997 (62 FR 40765), FDA published a proposed rule to implement the feed mill licensing provisions of the ADAA. The proposed rule would add a new part 515 to provide the requirements for medicated feed mill licensing. The proposed rule also would amend part 514 (21 CFR part 514) to remove the provisions regarding MFA's.

The proposed rule set forth the information to be included in medicated feed mill license applications and supplemental applications. The proposed rule also set forth the criteria for, among other things, the approval and refusal to approve a medicated feed mill license application, as well as the criteria for the revocation and/or suspension of a license.

The proposed rule provided conforming amendments to the Code of Federal Regulations (CFR) by removing references to ''MFA's'' and inserting appropriate references to "medicated feed mill licenses.'' Furthermore, the proposed rule clarified that the scope of the exemption from the requirement of establishment registration is identical to the scope of the exemption from the requirement of a medicated feed mill license. Finally, the proposed rule maintained the general scheme for categories and types of medicated feeds, and provided that those feeds exempted from the MFA requirement now would be exempt from being required to be manufactured in a licensed feed mill.

III. Discussion of Comments

A total of six parties submitted comments to the proposed rule. A discussion of the comments and FDA's responses follows:

A. Possession of Current Approved Labeling

1. Four comments objected to the requirement in proposed § 515.10(b)(6) that the license applicant commit to possess current approved Type B and/or Type C medicated feed labeling for each animal feed containing an approved new animal drug prior to receiving the Type A medicated article containing such drug. Furthermore, these comments objected to the related requirement in proposed § 510.305(b) (21 CFR 5 10.305(b)) that the medicated feed mill licensee maintain copies of approved labeling at the feed manufacturing facility for those Type B and/or Type C medicated feeds being manufactured. Two comments maintained that the possession by the feed manufacturer of labeling for the Type A medicated article, instead of the Type B and Type C medicated feed labeling, would satisfy the feed labeling requirements of the statute.

These four comments argued that the two proposed provisions, §§ 515.10(b)(6) and 5 10.305(b), would impose impractical requirements on feed mills, because the mills would be required to possess multiple feed labels for the use of each Type A medicated article before receipt of the Type A medicated article. These comments explained that because many Type A medicated articles may be used in multiple types of approved feeds, feed manufacturers typically do not know at the time of shipment of the Type A medicated article which feeds will be manufactured with the drug. Thus, these comments argued that the only way to satisfy the proposed rule's labeling requirement would be for the drug sponsor to ship in advance to the feed manufacturer the current approved labeling for all possible feeds that could be manufactured with each drug, and then for the feed manufacturer to maintain all of this labeling. The comments concluded that such a practice would pose a significant burden for both the drug sponsor and the feed manufacturer.

FDA has evaluated the comments and has concluded that the act, as amended by the ADAA, requires the licensed feed manufacturing facility to possess and maintain the current approved labeling for those Type B and/or Type C medicated feeds that will be manufactured at that facility prior to receiving the Type A medicated article(s) for these feeds. Section 512(a)(1) of the act, explicitly provides that at the time of removal of a Type A medicated article from a manufacturing, packing, or distributing establishment that the establishment have an unrevoked written statement from the licensed feed manufacturing facility, or a notice from the Secretary of Health and Human Services (the Secretary), that the facility has a medicated feed mill license and current approved labeling for the use of the Type A medicated article in animal feed. Section 5 12(a)(1) of the act provides that, in the absence of meeting these requirements, the new animal drug is deemed unsafe. A new animal drug deemed unsafe under section 5 12(a)(1) of the act is adulterated under section 501(a)(5) of the act (21 U.S.C. 351(a)(5)). Thus, the requirement in these regulations that the feed mill possess the current approved labeling is mandated by section 512(a)(l) of the act as amended by the ADAA.

Furthermore, FDA has concluded that the "approved labeling" required by the act and these regulations is that labeling submitted with and approved in the new animal drug application (NADA) for use of the feed containing the new animal drug (the "Blue Bird" label), not the labeling for the Type A medicated article as maintained by some comments.

Section 512(b)(I)(F) of the act requires an NADA for a new animal drug intended for use in animal feed to include "proposed labeling appropriate for such use" in animal feed as well as specimens of labeling for the drug itself. The regulations at § 514.1(b)(3)(v)(*a*) and (b)(3)(v)(b), which implement this provision, specifically require two sets of labels for new animal drugs for use in medicated feeds: "labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds" and "representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug." FDA refers to the representative labeling for the Type B and Type C medicated feeds as the "Blue Bird" label. This labeling is approved as part of the NADA. FDA believes that Congress intended feed mills to possess and maintain the labeling for use of the feed approved as part of the NADA since this provides the same level of public health protection that existed under the pre-ADAA system under which FDA approved the feed use labeling as part of the MFA and required such labeling to be maintained at the facility. Both systems ensure that each facility has the pertinent information to generate an actual feed label that is consistent with representative medicated feed labeling already approved by the agency.

The agency has concluded that the requirement that licensed feed manufacturers possess Blue Bird labeling for each medicated feed to be manufactured will not add a significant regulatory burden for industry. First, feed manufacturers have possessed and maintained feed labeling approved by FDA since the implementation of the new animal drug regulations in 1971 (36 FR 18375, September 14, 1971). Section 512(m)(l)(d) of the act and the regulations at § 514.2(b)(11) previously required feed manufacturers to submit for FDA's approval the proposed feed labeling with the MFA. Section 512(a)(1) of the act and the regulations at § 510.7 (21 CFR 5 10.7) also

required the feed manufacturer to possess the approved MFA, with the feed labeling, prior to shipment of the Type A medicated article for each feed. Furthermore, the regulations at § 5 10.305 previously required feed manufacturers to maintain the MFA, with the approved labeling, on site at the facility. Thus, this final rule's requirement that feed mill licensees possess and maintain feed labeling approved by FDA in the NADA (the Blue Bird label), as required by section 512(a)(1) of the act, is in essence the same as the feed manufacturer's previous legal obligation under the act to possess and maintain feed labeling approved by FDA.

Second, drug sponsors have submitted Blue Bird labels with the NADA as required by § 514.1(b)(3)(v)(*b*) (formerly § 135.4a(b)(3)(v)(*b*) (21 CFR 135.4a(b)(3)(v)(b))) since the implementation of the new animal drug regulations in 197 1 (36 FR 18375, September 14, 1971.) The requirement for the submission and approval of such labels with the NADA has ensured that these labels are available for distribution to feed manufacturers. Type A manufacturers, in turn, have been supplying approved Blue Bird labels to feed manufacturers since the development of these labels.

Third, feed manufacturers have been using Blue Bird labels as a model to generate actual feed labels and previously used such labels to satisfy the requirement for the submission of representative feed labeling with the MFA. Prior to this final rule, the new animal drug regulations required feed manufacturers to submit an MFA for each medicated feed with ''a copy of the final printed labeling," for approval by the agency (§ 135.4b(d); 36 FR 18375, September 14, 1971). Initially, FDA had accepted from the feed manufacturer only the actual feed label to satisfy this requirement. However, an FDA medicated feed task force, after consulting with the Animal Health Institute (AHI), the American Feed Industry Association (AFIA), and the Association of American Feed Control Officials (AAFCO), issued a report in December 1978 that recommended, among other things, that FDA accept "generic" labels with the MFA (Ref. 1). Soon after issuance of the task force's report, FDA allowed feed manufacturers to submit the Blue Bird label, rather than the actual feed label, with the MFA. The agency amended § 514.2(b)(11) to allow "labeling

representative of each intended use as stated in the claim" to be submitted with the MFA (51 FR 7382, March 3, 1986).

FDA has found that since approximately 1980, feed manufacturers have generally relied on the Blue Bird label in submitting the required labeling with the MFA. Feed manufacturers typically submitted with the MFA either a copy of the Blue Bird label or a label derived from the Blue Bird label (an equivalent Blue Bird label). An equivalent Blue Bird label listed the same active drug(s), claim(s), caution and/or warning statements, and mixing and feeding directions as listed in the Blue Bird label. The facility could then generate the actual feed label based on that labeling approved in the MFA. Since the equivalent Blue Bird label was approved as part of the MFA, the agency was assured that the labeling upon which the actual feed label was based correctly reflected the approval conditions of use for the feed.

As noted previously, Type A medicated article manufacturers frequently supplied the appropriate Blue Bird labels to the feed manufacturer for submission with the MFA. Thus, the requirement that the licensed feed manufacturer possess Blue Bird labeling for the feed being manufactured is consistent with industry practice.

FDA agrees with the comments that proposed § 515.10(b)(6) appeared to require a licensed feed mill to commit to possess approved labeling for all possible feeds that could be manufactured from the Type A medicated article. FDA does not intend that a licensed feed manufacturing facility must possess current approved labeling for Type B and/or Type C medicated feeds that the facility does not actually manufacture from the Type A medicated article. Thus, FDA is amending proposed § 515.10(b)(6) (in the final rule, § 515.10(b)(7)) to read, "A commitment that current approved Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug."

FDA notes that a feed manufacturer can satisfy the requirement to possess the current approved labeling by maintaining the Blue Bird labeling for each feed to be manufactured at the facility

in either paper or electronic format. To assist drug sponsors and feed manufacturers in the distribution of Blue Bird labels and to allow parties to determine more easily whether a feed mill is licensed, FDA has created a data base of medicated feed mill licensing information, available to the public on the Center for Veterinary Medicine's (CVM's) web site at ''http://www.fda.gov/cvm".

2. One comment argued that proposed §§ 510.305(b) and 515.10(b)(6) should not apply to medicated feed mill licensees because the majority of such licensees are firms with multiple facilities, where labeling is not created at the feed facility but in the home office. The comment claimed that these firms-use the published regulation of approval as the source of required information for the label. Furthermore, the comment argued that the proposed regulation would require such multiple facility firms to distribute Blue Bird labels from the home office to all of the facilities before obtaining the drug, which would serve no purpose. The comment noted that the proposed rule does not apply to nonlicensed facilities and stated that most of these facilities are single mill firms that may not have access to the labeling information in the **Federal Register,** CFR, Feed Additive Compendium, or to a computer with the capability to obtain this information free from the various information sources on the Internet. The comment concluded that the proposed rule's requirement for the possession of Blue Bird labeling should be eliminated, because ''[t]he present system of label development has worked well for the feed industry."

FDA has considered the previous comment and has concluded that the requirement that licensed feed mills possess Blue Bird labels will not add to the legal obligations with respect to feed labeling that existed for these mills prior to the enactment of ADAA. As discussed previously, before enactment of the ADAA, in accordance with section 512(m)(l)(D) of the act, feed firms submitted with the MFA the specimen of labeling to be approved for that feed. To satisfy this requirement firms typically chose to submit the Blue Bird label as the labeling specimen. Once FDA approved the MFA, the feed mill maintained a copy of the approved MFA, which included the approved labeling, under \$510.305. To comply with the conditions set forth in the

MFA for the manufacture of feed, the facility could then generate the actual feed label based on the approved labeling.

Under this rule implementing medicated feed mill licensing, firms that were previously required to have an approved MFA are now required to have a medicated feed mill license and the approved labeling for the manufacture of such feed. Just as the previous regulatory scheme required firms to possess labeling approved by FDA with the MFA for each feed to be manufactured, § 515.10(b)(7) of this rule requires firms to possess the approved labeling for such feed. The only distinction is that instead of the firm maintaining labeling for the feed that is approved by FDA in the medicated feed application process in addition to the NADA approval process, the firm will maintain the Blue Bird medicated feed labeling approved in the NADA. Additionally, § 510.305(b), as revised by this rule, requires that licensed firms maintain the approved labeling on the premises, which is consistent with the previous requirement for maintaining the MFA with a sample of the approved labeling. Thus, the requirements of this rule do not change the previous legal obligations of feed mills to possess and maintain approved labeling for the feed. Furthermore, as also discussed earlier in this preamble, since feed mills previously submitted the Blue Bird label or its equivalent for approval of an MFA, the requirements of this rule are consistent with the industry's method of feed label development.

For those firms where, labeling is created based on the CFR or other sources, FDA has concluded that a firm must possess and maintain the Blue Bird label to satisfy the requirements of section 512(a)(l) of the act, and §§ 515.10(b)(6) and 510.305(b) of this final rule. As discussed earlier in the preamble, the statutory requirement that licensed feed mills possess and maintain approved labeling for the feed ensures that these facilities rely on approved labeling to develop the actual feed labels. FDA is revising § 510.305 to clarify that if the home office of a multiple facility firm generates the actual feed labels and maintains the Blue Bird labels for all the feed the multiple facilities manufactures, then only the home office will be required to maintain the Blue Bird labels.

Finally, as for nonlicensed feed mills, such firms are not the subject of this regulation. Feed mills previously exempted from MFA's are also exempt from the licensing requirements set forth in this regulation. FDA previously exempted firms from the requirement that an MFA be approved for the manufacture of Type B and/or Type C medicated feed from Category I Type A medicated articles or from Category II Type B and/or Type C medicated feed, unless otherwise required by regulation. FDA exempted the manufacture of these feeds from the MFA requirements, including the submission of the labeling specimen, because any errors in the manufacture or labeling of such feeds would be unlikely to produce unsafe residues (§ 558.4(a); 51 FR 7382, March 3, 1986). Because nonlicensed facilities can manufacture only exempt feeds, FDA is not proposing that the requirements of §§ 510.305(b) and 515.10(b)(7) in the final rule apply to nonlicensed feed mills.

3. One comment argued that proposed § 510.305 should be amended so that a feed manufacturing firm with multiple establishments can maintain each license at its home office, while the firm simply maintains a "single readable document with relevant licensing information at each facility." Under § 510.305(d), as proposed, the home office of a multiple facility establishment can maintain the original licenses, but each facility must maintain a copy of the license. The license lists the requirements and commitments for the establishment, and it is very important that the people at the manufacturing site understand these requirements. Hence, it is very important that a copy of the license is maintained at each manufacturing facility. Thus, FDA has not changed § 510.305 as requested by the comment.

4. One comment requested that the agency hold a public meeting to discuss alternatives to the proposed rule regarding medicated feed labeling. The comment reasoned that such a meeting would give the agency the opportunity to hear and consider current industry methods and sources for developing labeling for medicated feeds. The comment stated that alternatively, interested members of the public could hold a round table for agency officials to provide the agency with input from industry compliance directors on the development of labeling.

In response to this comment, FDA participated in a meeting with representatives of AFIA and AH1 on March 17, 1998. AFIA and AHI presented their views, previously expressed in their written comments, regarding the feed labeling provisions of the medicated feed mill licensing proposed rule. The meeting helped the agency to understand the concerns of industry. Minutes of the meeting are included in Docket No. 97N–0276, and may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

B. Establishment Registration

5. One comment proposed that feed manufacturing facilities be exempt from the annual establishment registration requirement set forth in § 207.20 (21 CFR 207.20), so that all feed mills would be listed as exempt from this requirement under § 207.10 (21 CFR 207.10). The comment argued that establishment registration serves no purpose. The comment stated that one argument for establishment registration is that such registration is required yearly, and provides the agency with a list of who is registered and their locations. However, according to the comment, establishment registration has not achieved this goal in practice because neither CVM nor field enforcement offices have been provided numbers or locations of establishment registration facilities. The comment argued that, in any case, such information could be updated based on the agency's inspections of firms and the requests by firms for the withdrawal of medicated feed mill licenses.

The comment requests amendments to the registration requirements that are beyond the scope of this rulemaking. FDA is issuing these regulations to provide for medicated feed mill licensing in accordance with the ADAA. Therefore, FDA is not making any substantive changes to the scope of the registration exemption. With regard to the exemptions in § 207.10, FDA is amending the regulation merely to clarify, but not change, the scope of the registration exemption for medicated feed mill licensees. Furthermore, FDA is amending §§ 207.20 and 207.21 (21 CFR 207.21) in the regulations only to replace the phrase "medicated feed application" with the term "medicated feed mill license application."

Additionally, contrary to the comment's assertion, registration provides beneficial information to the agency that is not available from medicated feed mill licensing. Registration, unlike medicated feed mill licensing, is required annually by 21 CFR 207.22. FDA has found that firms comply with this requirement and provide annually the numbers and locations of registered facilities. This requirement allows FDA to determine which feed mills are still doing or intend to do business. Therefore, the agency believes the exemptions from registration should not be expanded.

C. Ninety-Day Approval Period

6. One comment noted that proposed § 5 15.20 provides the agency 90 days to act upon a medicated feed mill license application. The comment further noted that the agency did not require the 90 days set forth by regulation to process medicated feed applications, but instead the agency provided the industry timely approvals that ensured that facilities were not placed at a competitive disadvantage. Thus, the comment concluded that 30 days would better reflect the time requirements for acting on a medicated feed mill license application, particularly because a medicated feed mill license approval does not involve the agency's review of the medicated feed labeling.

FDA rejects the suggestion that proposed § 5 15.20 be changed to allow the agency only 30 days to act on a medicated feed mill license application. First, section 512(m)(2) of the act sets forth explicitly the time limit of 90 days for agency action. Second, almost all feed mills applying for a license will require a preapproval inspection by FDA conducted after filing of the medicated feed mill license application, and it would not be feasible for FDA, in all cases, to conduct the preapproval inspection within 30 days of filing of the application. Of course, as with MFA's, FDA will continue to act as expeditiously as possible in processing license applications.

D. Requirements for Drug Sponsors

7. Three comments noted that the agency accidentally omitted a revision of § 5 10.7 (2 1 CFR 5 10.7) (consignees of new animal drugs for use in the manufacture of animal feeds) in the licensing

proposal. The comments suggested that the reference in $5 10.7(a)(1) to ‘‘§ 5 14.2” should be changed to ‘‘§ 515.10.” The comments stated that such a change would be consistent with the deletion of § 514.2 (applications for animal feeds bearing or containing new animal drugs) and the establishment of § 515.10 (applications for licenses to manufacture animal feeds bearing or containing new animal drugs).

FDA agrees that in order to be consistent with § 515.10 of these regulations, the reference should be changed as noted in the comments. Furthermore, in order to be consistent with the language of the ADAA, FDA has concluded that § 510.7 must also clarify that at the time of a new animal drug’s removal from the establishment of a manufacturer, packer, or distributor of a Type A medicated article, such manufacturer, packer, or distributor must possess an unrevoked written statement from the consignee, or notice from the Secretary, that the consignee holds a medicated feed mill license and has in its possession current approved labeling for the drug in animal feed. Thus, § 5 10.7(a)(1) has been amended to read as follows: “Holds a license issued under § 515.20’’.

A drug sponsor can satisfy this requirement by receiving written confirmation from the facility as to its feed mill license number or by verifying the feed mill’s license status on CVM’s web site. The confirmation and/or identification of a feed manufacturing facility’s license number indicates that the firm should possess current approved labeling, because the firm must commit to the possession of such labeling in the medicated feed mill license application. The drug sponsor’s verification from the FDA web site of an approved facility’s license number would constitute ‘ ‘notice from the Secretary’ ’ that the feed mill possesses a license and the current approved feed labeling. Section 5 10.7(a)(2) has also been amended to reference the new § 515.10 regulation. As provided in section 5 12(a)(1)(B)(ii) of the act, if the consignee is not the user of the drug the shipper must obtain an unrevoked written statement from the consignee that the consignee will ship such drug only to a holder of an approved application under § 5 15.10 of this chapter.

E. Status of Related Citizen Petitions

8. One comment expressed disappointment and concern that the agency was unable to resolve pending issues in order to publish proposed rules for two citizen petitions on drug assays (Docket No. 95P–0373) and on medicated liquid feeds (Docket No. 93P–0174) as part of this rulemaking. The comment further stated that these two petitions suggest significant and appropriate changes to the current good manufacturing practices (CGMP's) and would have saved the agency much time and resources if the agency had published responses concurrently or incorporated such responses in the published proposal on medicated feed mill licenses. The comment stated that the medicated liquid feed petition is long overdue for rulemaking as the agency provided a letter to AFIA on April 19, 1995, that essentially agreed with the substance of AFIA's petition and indicated that a proposal to amend 21 CFR 558.5 was being prepared at that time. The comment urged the agency to act on these two petitions and publish proposed rules to resolve these impasses on serious issues related to the regulation of medicated feed.

FDA is well aware of the two citizen petitions and is actively reviewing these petitions. In preparing this proposal, FDA concluded that incorporating any amendments to the regulations based on these petitions would have unduly delayed the publication of this final rule. The agency plans to develop proposed rules related to these citizen petitions following publication of this final rule.

FDA notes that in a March 30, 1998, amendment to the AFIA and AHI 1995 Citizen Petition (Docket No. 95P–0373) AFIA and AHI withdrew their request to amend § 510.301 (21 CFR 510.301). However, following publication of this final rule FDA intends to develop a proposed rule to amend § 510.301 to be consistent with the requirements of the ADAA.

F. Enforcement Policy

9. One comment requested that the agency take swift and positive compliance action against those firms found to be in violation of CGMP's. FDA recognizes that a visible and firm regulatory posture is essential so that medicated feeds are manufactured, labeled, and distributed in a safe

manner. FDA is prepared to take the necessary steps to ensure the safe and effective use of animal drugs in animal feeds.

IV. Additional Changes

FDA has reordered and rewritten subpart A of part 15 to make it more logical and consistent.

V. Environmental Impact

FDA has carefully considered the potential environmental impacts of this rule. The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Medicated feed mill licensing is a procedure established by the ADAA as a replacement for FDA's previous MFA system. The final rule substitutes a facility licensing program for a system of feed-by-feed approval to manufacture feeds containing approved new animal drugs, thereby substantially reducing the number of approval requests required from facilities manufacturing feeds containing new animal drugs. A medicated feed mill license authorizes a feed mill to manufacture any feed containing an approved new animal drug. Previously, a feed mill was required to submit an MFA to manufacture each applicable feed containing an approved new animal drug.

This streamlining does not reduce the responsibility of each facility to manufacture medicated feeds in full compliance with CGMP's regulations. Additionally, the final rule does not prevent FDA from inspecting facilities and their records or taking actions to bring facilities into compliance.

The licensing of a feed mill by FDA does not reduce or change the responsibilities of the mill management to comply with requirements of other Federal, State, or local workplace waste management and emissions laws and regulations. Consistent failure of a facility to comply with hazard communication requirements, to provide necessary worker protection, or to adequately manage wastes could be regarded by FDA as an indication that the facility has a systemic problem that calls into question the ability of the feed mill to comply with FDA CGMP's regulations.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 or more (adjusted annually for inflation) million in any one year.

The agency has reviewed this final rule and has determined that the rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA believes that the rule is consistent with the regulatory philosophy and principles identified in the Executive Order and will not have a significant effect on a substantial number of small entities. The Office of Management and Budget has determined that this final rule is a significant regulatory action subject to review under the Executive Order. Also, since the expenditures required by the rule are under $100 million, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

With this rule, FDA is streamlining existing paperwork requirements by amending the process for obtaining approval to manufacture medicated feeds. Instead of requiring an MFA for each applicable medicated feed, this final regulation requires only a single facility license per feed mill, as appropriate. The ADAA granted a transitional license, valid for 18 months, to all feed manufacturing facilities that held an approved MFA. During this time, the facilities could obtain

a permanent license by submitting a license application and a copy of an approved MFA to FDA. All other existing reporting responsibilities for each drug remain unchanged.

In its analysis for the proposed rule, the agency had assumed that the only costs to be incurred by industry would be the paperwork costs associated with applying for a facility license. FDA estimated that approximately 2,000 feed mills would be affected by this rule, and that it would take approximately 15 minutes for each facility to complete its application. Taking 1995 median weekly earnings of $684 (Ref. 2) for the executives, administrators, and managers who would complete the applications, and adding 40 percent for fringe benefits, yielded average hourly earnings of $23.94. Thus, the agency estimated a combined paperwork cost for all facilities totaling $11,970 for the first year, and $600 for the estimated 100 mills expected to apply for licensing in each subsequent year. In addition, FDA estimated annual costs of $530 for all of those facilities completing paperwork in reference to license supplements, the voluntary revocation of their license, or hearing procedures. The total cost equaled approximately $6 per mill.

FDA has inflated these costs in the final rule to account for the increase in employment costs from 1995 to 1999. Using the average annual increase of 3.35 percent from 1995 to 1998 over the 4 years from 1995 to 1999, FDA estimates that the combined paperwork costs would total $13,735 in the first year and about $700 in each subsequent year (Ref. 3). Further, paperwork costs in reference to license supplements, voluntary revocation of licenses and hearing procedures would amount to about $600 annually.

Several comments to the proposed rule indicated that additional costs would be incurred due to the labeling requirements of the rule. The agency acknowledges that the costs for feed mills maintaining and retrieving Blue Bird labels was not estimated in the proposal. In Table 3 of section VIII of this document, a total cost to the industry of 500 hours is estimated for a total of 2,000 licensees. At the inflation-adjusted $27.47 per hour, the agency estimates that maintaining and retrieving the labels will cost the industry an additional $13,735 annually. Total industry costs would amount to only about $14 per mill.

For the proposed rule, the agency had estimated a large savings in the paperwork burden due to the elimination of the MFA requirements. Over the past 5 years, the agency has received approximately 3,300 MFA's per year including both original applications and MFA supplements. In the past, FDA surveyed several feed mills and animal drug manufacturers, and determined that it took industry about 2 hours to complete an MFA application. Therefore, FDA estimated that the rule would save industry over $158,000 per year, or approximately $79 per mill per year, on average. FDA has adjusted this saving for wage inflation to approximately $18 1,000 per year, or about $91 per mill each year. The mills that have routinely submitted a larger number of MFA's would realize a larger sayings than those mills that routinely submit few MFA's. The agency did not receive comments on this estimate and retains the inflation-adjusted amount for the final rule.

FDA also predicted that it would experience an administrative cost saving in response to the medicated feed mill licensing requirement. Since 1994, the agency has spent approximately $180,000 per year for a contractor to process the MFA's. In contrast, it would take FDA only about 40 minutes to process each medicated feed mill license application, at a cost of $25 per hour for a GS-13 government employee. The first year, the agency estimated that it would cost $33,500 to process the expected 2,000 applications, and $10,000 for starting up a tracking and indexing computerized data base. Further, it would cost only about $1,700 to process the 100 applications for each year thereafter.

Adjusting for wage inflation for the final rule, the agency expects the first year cost to process the applications to be about $37,200, and $11,500 for the tracking and indexing computerized data base. Application processing for subsequent years is expected to cost about $1,850 per year. The agency did not receive comments on these estimates of government cost savings and retains the inflation-adjusted amounts for the final rule.

The Small Business Administration (SBA) defines all manufacturers of prepared feeds and feed ingredients for animals and fowls having 500 employees or less as a small business. The agency previously estimated that approximately 20 percent of the affected feed mills belong to

large conglomerates that have an overall employee count higher than 500. Therefore, the remaining 80 percent of the affected facilities would be considered small feed mills by SBA's standards. However, as described previously, the agency has determined that the rule will provide a net economic savings for all facilities. Therefore, in accordance with the Regulatory Flexibility Act, FDA certifies that this rule will not have a significant effect on a substantial number of small entities.

VII. Federalism

FDA has analyzed the final rule in accordance with the principles and criteria set forth in Executive Order 13 132 and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given as follows. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing each collection of information.

Title: Medicated Feed Mill License Application.

Description: This final rule implements the ADAA's medicated feed mill licensing provisions. It requires that any medicated feed manufacturing facility seeking a license submit an application to FDA. In § 5 15.10 of the final regulations, FDA proposed that medicated feed mill license applications be submitted on FDA Form 3448, "Medicated Feed Mill License Application."

Section 5 15.11 of the final regulation specifies that supplemental applications must be submitted for a change in ownership and/or change in mailing address, which also would be submitted on FDA Form 3448. Furthermore, § 515.23 of the regulations provides for voluntary

revocation of a license. A medicated feed licensee would submit, in writing to FDA, a request for voluntary revocation of a license.

Finally, § 5 15.30 of the regulation provides procedures refusing to approve license applications when, among other reasons, the application is incomplete, false or misleading or the manufacturing, processing, and packaging of the animal feed do not comply with applicable provisions of the act. A medicated feed manufacturing facility would have the option to submit a request in writing for a hearing in response to the agency's proposal to refuse to approve a medicated feed mill application.

Description of Respondents: Medicated Feed Manufacturing Facilities.

In the **Federal Register** of July 30, 1997 (62 FR 40765), interested persons were requested to send comments regarding this collection of information to OMB by August 29, 1997. In response to this notice OMB received one comment regarding the paperwork aspect of this collection of information. The comment argued that the agency's estimate of the burden of the proposed collection of information was inaccurate in the following two instances: (1) In assuming that the only costs that will be incurred are the paperwork costs associated with applying for a facility license, and (2) in the estimate of $10,000 for tracking and indexing a computerized data base.

Regarding instance (1), the comment stated that the agency's assumption is inaccurate in that no consideration has been given to the capital and operating costs for the retrieval and maintenance of approved labeling for medicated feeds. The comment stated that this burden applies to sponsors under section 512(a)(l)(B) of the act and to licensed feed mills under proposed § 510.305.

CVM has evaluated this part of the comment and agrees that the agency did not address the cost for the licensed feed mill to maintain and retrieve approved Blue Bird labels as required under § 5 10.305. Table 3 of this document provides an estimate of that cost at a total of 500 hours annually for an estimated 2,000 licensees. This covers the cost of obtaining the label from either the drug sponsor or FDA and keeping it in a file. CVM estimates that most licensed feed establishments would only have 1 to 10 Blue Bird labels to maintain and retrieve. A few, primarily

at their home office. Thus the average estimate of 15 minutes per licensee takes these factors into account.

The agency has concluded that it did not err in excluding this burden for drug sponsors because the provision the comment cited, which requires retrieval and maintenance of approved labeling, applies only to feed mills, not to sponsors. The burden is on feed mills to retrieve the approved labeling either from the sponsor or FDA.

Regarding instance (2), the comment maintained that unless access to this data base is made available to sponsors and consignees, it would be logical to assume that similar expenses would be incurred by each sponsor and consignee maintaining a parallel data base in order to ensure their compliance with section 5 12(a)(l)(B) of the act. The comment argued that the most effective approach to eliminate this unnecessary burden would be for CVM to provide public access to its data base through the CVM home page. FDA has evaluated this comment, and CVM has put a list of approved licensees on the Internet, and public access has been granted.

FDA had estimated that 2,000 respondents would apply for feed mill licenses under § 5 15.10 during the first year and that a total of 500 hours would be required for them to respond. During the first 18 months (by the transition provisions, respondents had 18 months to obtain a license), only 1,250 respondents applied for licenses. FDA estimated that during each succeeding year, 100 new respondents would request feed mill licenses. Based on current information, that number appears to be a reasonable estimate of the number of respondents. The agency has received approximately 70 requests for licenses in the year following the first 18 months. FDA also estimated that there would be 25 respondents for supplemental applications (§ 5 15.1 1), 50 for voluntary revocations (§ 5 15.23), and 0.15 for notices of opportunity for hearing (§ 5 15.30). Those numbers also appear to have been reasonable estimates.

This final rule contains the original provisions of part 5 15, as proposed, and amends these provisions only for further clarity. As a result of the comment(s) received, an estimate of an annual recordkeeping burden (Table 3) has been added to the burden chart, under § 5 10.305. Thus, the

recordkeeping burden (Table 3) has been added to the burden chart, under § 5 10.305. Thus, the original annual reporting burden estimate has been changed to include annual recordkeeping requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN: FIRST YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	2,000	1	2,000	0.25	500
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6
Total					522.1

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN: EACH SUCCEEDING YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	100	1	100	0.25	25
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6
Total					47.1

'There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN*

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	2,000	1	2,000	0.25	500

[1] There are no capital cost or operating and maintenance cost associated with this collection of information.

Individuals or organizations may submit comments on this burden estimate or any other aspect of these collection of information provisions, including suggestions for reducing the burden, and direct them to William Price (address above).

The information collection provisions in this final rule have been approved under OMB control number 0910-0356. This approval expires October 31, 2000. An agency may not conduct or sponsor, and a person is not required to provide, a collection of information unless the collection of information displays a currently valid OMB control number.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Medicated Feed Task Force, "Medicated Feed Task Force Report," December 1978.

2. Employment and Earnings, U.S. Department of Labor Bureau and Labor Statistics, vol. 43, No. 1, p. 205, January 1996.

3. U.S. Department of Labor Bureau of Labor Statistics; ''ftp://ftp.bls.gov/pub/special.requests/lf/aat39.txt''.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 514 and 51.5

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended to read as follows:

PART 207--REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: 21 U.S.C. 331,351, 352, 355, 360, 360b, 371, 374; 42 U.S.C. 262.

2. Section 207.10 is amended by revising paragraph (f) to read as follows:

§ 207.10 Exemptions for domestic establishments.

* * * * *

(f) Persons who only manufacture the following:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds, and/or;

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(3) Persons who manufacture free-choice feeds, as defined in § 5 10.455 of this chapter, or medicated liquid feeds, as defined in § 558.5 of this chapter, where a medicated feed mill license is required are not exempt.

* * * * *

§ 207.20 [Amended]

3. Section 207.20 *Who must register and submit a drug list* is amended in paragraph (c) by removing the words “medicated feed application,” and adding in its place “medicated feed mill license application,“.

§ 207.21 [Amended]

4. Section 207.21 *Times fur registration and drug listing* is amended in paragraph (a) in the second sentence, by removing the words "medicated feed application," and adding in its place "medicated feed mill license application,".

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

5. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351,352, 360b, 371, 374.

6. Section 225.1 is amended by revising paragraph (b)(2) and by adding paragraph (c) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(b)(1) * * *

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which an approved license is not required.

(c) In addition to the recordkeeping requirements in this part, Type B and Type C medicated feeds made from Type A articles or Type B feeds under approved NADA's and a medicated feed mill license are subject to the requirements of § 510.301 of this chapter.

7. Section 225.58 is amended in paragraph (b)(l) by revising the first sentence to read as follows:

§ 225.58 Laboratory controls.

* * * * *

(b) * * *

(1) For feeds requiring a medicated feed mill licence (Form FDA 3448) for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter.
* * *

* * * * *

8. Section 225.115 *Complaint files* is amended by revising paragraph (b)(2) to read as follows:

$225.115 Complaint files.

* * * * *

(b) * * *

(2) For medicated feeds whose manufacture require a medicated feed mill license (Form FDA 3448), records and reports of clinical and other experience with the drug shall be maintained and reported, under § 510.301 of this chapter.

PART 510—NEW ANIMAL DRUGS

9. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321,331, 351, 352,353, 360b, 371, 379e.

10. Section 510.7 is amended by revising paragraphs (a)(l) and (a)(2) to read as follows:

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) * * *

(1) Holds a license issued under § 5 15.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 5 15.10 of this chapter.

* * * * *

11. Section 510.301 is amended to revise the section heading to read as follows:

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

* * * * *

12. Section 510.305 is revised to read as follows:

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

PART 514—NEW ANIMAL DRUG APPLICATIONS

13. The authority citation for 21 CFR part 5 14 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

5514.2 [Removed]

14. Section 514.2 *Applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.9 [Removed]

15. Section 514.9 *Supplemental applications for animal feeds bearing or containing new animal drugs* is removed.

5514.105 [Amended]

16. Section 514.105 *Approval of applications* is amended by removing the introductory text of paragraph (a) and by removing paragraph (b), and by redesignating paragraphs (a)(1) and (a)(2) as paragraphs (a) and (b), and by amending newly redesignated paragraph (a) by removing the first word “He” and adding in its place “The Commissioner ’’.

$514.111 [Amended]

17. Section 514.111 *Refusal to approve an application* is amended by removing paragraph (b) and by redesignating paragraph (c) as paragraph (b).

5514.112 [Removed]

18. Section *5* 14.112 *Return of applications for animal feeds bearing or containing new animal drugs* is removed.

5514.115 [Amended]

19. Section 514.115 *Withdrawal of approval **of** applications* is amended in paragraphs (a), (b), (c), and (d) by removing the phrase “or (m)(2)“; in paragraph (c)(1) by removing the phrases “or (m)(5)(A)” and “or (m)(5)(B)“; in paragraph (c)(3) by removing the phrase “or animal feed’, and in paragraph (e) by removing the second sentence.

20. Section 514.201 is revised to read as follows:

§ 514.201 Procedures for hearings.

Hearings relating to new animal drugs under section 5 12(d) and (e) of the act shall be governed by part 12 of this chapter.

2 1. Part 5 15 is added to read as follows:

PART 515—MEDICATED FEED MILL LICENSE

Subpart A-Applications

Sec.

Subpart B-Administrative Actions on Licenses

Subpart C-Hearing Procedures

Subpart D-Judicial Review

Authority: 2 1 U.S.C. 360b, 37 1.

Subpart A-Applications

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Forms FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine home page at ''http://www.fda.gov/cvm''.

(b) A completed medicated feed mill license must contain the following information:

(1) The full business name and address of the facility at which the manufacturing is to take place.

(2) The facility's FDA registration number as required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act).

(3) The name, title, and signature of the responsible individual or individuals for that facility.

(4) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published under section 512(i) of the act.

(5) A certification that the methods used in, and the facilities and controls used for, manufacturing, processing; packaging, and holding such animal feeds conform to current good manufacturing practice as described in section 501(a)(2)(B) of the act and in part 225 of this chapter.

(6) A certification that the facility will establish and maintain all records required by regulation or order issued under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, and will permit access to, or copying or verification of such records.

(7) A commitment that current approved Type B and/or Type C medicated feed labeling for each Type B and/or Type C medicated feed to be manufactured will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.

(8) A commitment to renew registration every year with FDA as required in §§ 207.20 and 207.2 1 of this chapter.

(c) Applications must be completed, signed, and submitted to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(d) Applications that are facially deficient will be returned to the applicant. All reasons for the return of the application will be made known to the applicant.

(e) Upon approval, the original copy of the application will be signed by an authorized employee of FDA designated by the Commissioner of Food and Drugs, and a copy will be returned to the applicant.

g515.11 Supplemental medicated feed mill license applications.

(a) After approval of a medicated feed mill license application to manufacture animal feed, a supplemental application shall be submitted for a change in ownership and/or a change in mailing address of the facility site.

(b) Each supplemental application should be accompanied by a fully completed Form FDA 3448 and include an explanation of the change.

(c) Within 30 working days after a supplemental application has been filed, if the Commissioner of Food and Drugs determines that the application provides adequate information respecting the change in ownership and/or postal address of the facility site, then an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448. Supplemental applications that do not provide adequate information shall be returned to the applicant and all reasons for the return of the application shall be made known to the applicant.

Subpart B-Administrative Actions on **Licenses**

§ 515.20 Approval of medicated feed mill license applications.

Within 90 days after an application has been filed under § 515.10, if the Commissioner of Food and Drugs (the Commissioner) determines that none of the grounds for denying approval specified in section 512(m)(3) of the Federal Food, Drug, and Cosmetic Act (the act) applies, an authorized employee of the Food and Drug Administration designated by the Commissioner shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448.

§ 515.21 Refusal to approve a medicated feed mill license application.

(a) The Commissioner of Food and Drugs (the Commissioner) shall within 90 days, or such additional period as may be agreed upon by the Commissioner and the applicant, after the filing of an application under § 5 15.10, inform the applicant in writing of his/her intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, on the basis of a preapproval inspection, or upon the basis of any other information before him that:

(1) The application is incomplete, false, or misleading in any particular; or

(2) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(3) The facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published under section 512(i) of the act.

(b) The Commissioner, as provided in § 515.30, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless

by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

§ 515.22 Suspension and/or revocation of approval of a medicated feed mill license.

(a) The Secretary of Health and Human Services may suspend a medicated feed mill license approved under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) and give the person holding the medicated feed mill license application prompt notice of this action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended.

(b) The Commissioner of Food and Drugs (the Commissioner) shall notify in writing the person holding an application approved under section 5 12(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing a supplemental application under § 5 15.11.

(c) The Commissioner may notify in writing the person holding an application approved under section 5 12(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under sections 5 12(m)(5)(A) or 504(a)(3)(A) of the act, or

the applicant has refused to permit access to, or copying,or verification of, such records as required by sections 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

§ 515.23 Voluntary revocation of medicated feed mill license.

A license issued under section 5 12(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under § 558.4(b) of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section.

Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

§ 515.24 Notice of revocation of a medicated feed mill license.

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) is revoked by the Commissioner of Food and Drugs (the Commissioner), the Commissioner will give appropriate public notice of such action by publication in the **Federal Register.**

§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

The Commissioner of Food and Drugs (the Commissioner), upon his/her own initiative or upon request of an applicant stating reasonable grounds therefor and if the Commissioner finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

5515.26 Services of notices and orders.

All notices and orders under this part 5 15 and section 5 12 of the Federal Food, Drug, and Cosmetic Act (the act) pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at the applicant or respondent's last known address in the records of the Food and Drug Administration.

Subpart C-Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license

application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the **Federal Register** and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration

of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

9515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 5 12(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D-Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 558-NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

22. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: U.S.C. 360b, 371.

§ 558.3 [Amended]

23. Section *558.3 Definitions and general considerations applicable to this part* is amended in paragraphs (b)(3) and (b)(4) by removing the phrase ' 'an application approved under § 514.105(b) of this chapter" and adding in its place "a medicated feed mill license application

approved under § 515.20 of this chapter"; and in paragraphs (b)(2) and (b)(5) by removing "$514.105(a)" and adding in its place ''§ 514.105".

24. Section 558.4 is amended by revising the section heading and paragraphs (a), (b), and (c) to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

* * * * *

Dated: 8/12/99

August 12, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

['Margaret M.' Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99–???? Filed ??-??-99; 8:45 am]

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